

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**GENERAL INFORMATION**KU83629

FEB 19 2009

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| Trade Name | SMOOTHSHAPES® SYSTEM |
| Classification Name | LASER INSTRUMENT, SURGICAL, POWERED |
| Class | II |
| Product Code | NUV |
| CFR section | 878.4810 |
| Device panel | General & Plastic Surgery |
| Legally marketed predicate devices | Eleme SmoothShapes (K053611; K061603) Syneron Velashape (K071872) |
| Submitter | Elemé Medical, Inc. Heron Cove Office Park 10 Al Paul Lane, Suite 102 Merrimack, NH 03054 |
| Contacts | Michail A. Pankratov, Vice President, Clinical & Regulatory Affairs mpankratov@elememedical.com Phone: 1-603-816-1645 Fax: 1-603-882-4762 |

DEVICE DESCRIPTION

The SmoothShapes® System featuring Photomology® technology is designed to offer an innovative way to safely and effectively treat cellulite. The proprietary Photomology technology combines heating through dynamic energy (laser and light) with mechanical manipulation (contoured rollers and vacuum) to reduce the appearance of cellulite.

INTENDED USE

The Elemé Medical SmoothShapes® system is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

SUBSTANTIAL EQUIVALENCE

The SmoothShapes® Systems is substantially equivalent to the predicate devices with respect to technological features and intended use.

The modification of increased optical power does not affect the fundamental scientific technology of the device or its Intended use. The modification of increased optical power does not raise new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eleme Medical, Inc.
% Michail Pankratov, MD, PhD
VP, Regulatory & Clinical Affairs
10 Al Paul Lane, Suite 102
Merrimack, New Hampshire 03054

FEB 19 2009

Re: K083629

Trade/Device Name: SMOOTHSHAPES® System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: NUV

Dated: January 22, 2009

Received: January 23, 2009

Dear Dr. Pankratov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

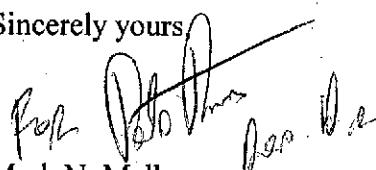
Page 2 – Michail Pankratov, MD, PhD

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE510(k) Number (if known): K083629Device Name: **SMOOTHSHAPES® System**

Indications for Use:

The Elemé Medical SmoothShapes® system is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. K. Johnson, Jr., M.D.
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083629